#### REMARKS

Claims 18-29 and 31-36 remain in this application. Claim 17 has been canceled, and claims 1-16 and 30 were previously canceled. Claims 28, 29 and 34 have been withdrawn.

Claims 18, 20-23, 26-27, 31-33, and 35-36 have been amended. New claims 37-41 have been added. Upon entry of this amendment, claims 18-29 and 31-41 are pending.

Support for the amended and the new claims can be found in the specification and in the original claims as filed. Support can be found, for example, at paragraphs [0031], [0032], [0033], [0036], and [0059] of the corresponding US Patent Application Publication (US 2008/0171076A1). Thus, no new matter has been added.

#### TRADEMARK

At page 4, item 3, the Office Action notes the use of Trademarks in the specification and requests that the trademarks be capitalized. The amended specification correctly indicates the use of trademarks, for example, in the Examples at pages 17-19.

#### **OBJECTIONS**

At pages 5-6, items 4-8, the Office Action objects to claims 17, 26, 27, 35 and 36 for informalities. Applicants respectfully traverse the objections.

The features of claim 17 have been incorporated into amended claim 18 and claim 17 has been canceled. In claim 18, the amino acid sequence (SEQ ID NO:10) has been added to the sequence listing, and the peptide includes a sequence identifier (SEQ ID NO:10).

Amended claims 26, 27, 35 and 36 address the informalities noted in the Office Action.

Accordingly, Applicant's respectfully request reconsideration and withdrawal of the claim objections.

At page 6, items 9-11, the Office Action objects to the specification for informalities. The amended specification addresses each of the informalities. The amended specification provides correct and consistent "SEQ ID NO" designations as pages 3, 8, 12, 15, 17 and 19. The sequence of formula 1 on page 3 designates the peptide as SEQ ID NO:10.

The amended specification further contains section headings.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the objections to the specification.

## 35 U.S.C. § 112, SECOND PARAGRAPH

At page 7, item 13, the Office Action rejects claims 17-27, 31-33 and 35-36 under 35 U.S.C. 112, second paragraph, as being indefinite. The Office Action holds the position that it is

unclear what is encompassed within a "derivative" of an amino acid. Applicants respectfully traverse the rejection.

Amended claim 18 now recites the features of claim 17, and claim 17 has been canceled. Amended claim 18 is directed to a composition comprising a protein fragment, wherein the protein fragment is a synthetic peptide of SEQ ID NO:10. The peptide of SEQ ID NO:10 comprises specific amino acids but does not include broadly claimed "derivative" amino acids. Amended claim 18 clearly and distinctly recites the claimed subject matter. Each of claims 18-27, 31-33, 35-36 and new claims 37-41 satisfies the requirements of 35 U.S.C. §112, second paragraph. Accordingly, Applicant's respectfully request reconsideration and withdrawal of the rejection.

## 35 U.S.C. § 112, FIRST PARAGRAPH

At page 8, item 16, the Office Action rejects claims 17-27, 31-33 and 35-36 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse the rejection.

Amended claim 18 incorporates the features of claim 17 and claim 17 has been canceled. Claim 18 is directed to a composition comprising a protein fragment of the uncoupling protein (UCP) family. The protein fragment is a synthetic peptide of the following formula:

AA)n-Pro-X1-X2-X1-X3-Lys-X1-Arg-X4-X5-(AA)n (SEQ ID NO:10),

wherein

X1 = Leu, Thr, or Val,

X2 = Asp, or Glu,

X3 = Ala, or Val,

X4 = Leu, Phe, or Tyr,

X5 = Gln, Ile, or Met,

(AA) is any amino acid, and

n is a whole number ranging from 0 to 2.

The protein fragment further comprises a synthetic peptide selected from the group consisting of SEQ ID NO:1 - SEQ ID NO:9. The specification provides sufficient written description for such a composition.

Each of the synthetic peptides within the scope of claim 18 share a single structural feature, the formula of SEQ ID NO:10. The specification presents a sufficient number of representative species which encompass that genus. The specification clearly defines and provides examples of what qualifies as compounds of claimed invention. The specification further provides a correlation between the structure and function of the claimed compounds. Amended claim 18, dependent claims 19-27, 31-33 and 35-36, as well as new claims 37-41, all satisfy the requirements of 37 U.S.C. § 112, first paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

At page 14, item 17, the Office Action rejects claims

Docket No. 0591-1010 Appln. No. 10/589,863

17-18, 20-27, 31-33 and 35-36 under 35 U.S.C.  $\S$  112, first paragraph as lacking enablement. Applicants respectfully traverse the rejection.

As stated above, amended claim 18 recites features from original claim 17, and claim 17 has been canceled. Claim 18 is directed to a composition comprising a protein fragment of the UCP family as an active ingredient, wherein the protein fragment is a synthetic peptide of the following formula:

 $AA) \, n - Pro - X1 - X2 - X1 - X3 - Lys - X1 - Arg - X4 - X5 - (AA) \, n \quad (SEQ \ ID \ NO:10) \, ,$  wherein

X1 = Leu, Thr, or Val,

X2 = Asp, or Glu,

X3 = Ala, or Val,

X4 = Leu, Phe, or Tyr,

X5 = Gln, Ile, or Met,

(AA) is any amino acid, and

n is a whole number ranging from 0 to 2.

The protein fragment further comprises a synthetic peptide selected from the group consisting of SEQ ID NO:1 - SEQ ID NO:9.

Currently amended claim 18 features a synthetic peptide of limited size, i.e. 10 - 14 amino acids. Three of the amino acids: Pro, Lys and Arg are of fixed identity. Seven amino acids, X1 - X5, are of very limited identity (2-3 amino acids). Thus, the breadth of claim 18 is limited to a peptide of relatively few possible combinations of amino acids. Amended

claim 18 further recites that the protein fragment comprises a synthetic peptide selected from a group consisting of SEQ ID NO:1 - SEQ ID NO:9, further limiting the breadth of the claim. In general, most of the possible substitutions and variations within these peptides are conservative and/or between chemically equivalent amino acids wherein the peptide will retain its essential properties. Any peptide encompassed by the claimed invention would behave similarly, and one would not be burdened with any undue experimentation to screen the limited compounds to find those that have the desired activities.

Each of the limited number of peptides could display differing amounts of activity in the claimed composition. Applicants acknowledge that even a single amino acid substitution can change the activity of the peptide. The claims are directed to a compostion comprising a protein fragment of the UCP family as an active ingredient. The claims, however, do not recite any feature related to the level of activity of the composition.

Amended claim 18 is directed to a composition comprising a defined set of protein fragments. The specification provides sufficient guidance to enable one of ordinary skill in the art to make such a composition. A composition comprising one or more of the featured synthetic peptides may not have the same activity as another composition comprising different synthetic peptides.

For all of these reasons, claim 18, claims 19-27, 31-33

and 35-36, as well as new claims 37-41, are all fully enabled by the specification, and satisfy the requirements of 35 U.S.C. § 112, 1st paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

## CLAIM REJECTION - 35 U.S.C. § 101

At page 23, item 19, the Office Action rejects claims 17-27, 31-33 and 35-36 under 35 U.S.C. § 101, as directed to non-statutory subject matter. Applicants respectfully traverse the rejection.

Claim 17 has been canceled, and claim 18 is directed to a composition comprising a protein fragment of the UCP family as an active ingredient, wherein the protein fragment is a synthetic peptide of the formula of SEQ ID NO:10. As a <u>synthetic</u> peptide, the protein fragment is statutory subject matter. Thus, claim 18, claims 19-27, 31-33 and 35-36, and new claims 37-41, are each directed to statutory subject matter. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

## CLAIM REJECTION 35 U.S.C. § 102(b)

At page 24, item 21, the Office Action rejects claim 1 (i.e. claim 17) under 35 U.S.C. § 102(b) as anticipated by NI et al. (US 2003/0036646A1). Applicants respectfully traverse the rejection.

The Office Action cites NI for teaching uncoupling protein family peptides that allegedly meet the limitations of SEQ ID NO:10. Amended claim 18, however, recites that the protein fragment comprises a synthetic peptide selected from the group consisting of SEQ ID NO:1 - SEQ ID NO:9. NI fails to teach or suggest these synthetic peptides. For at least this reason, NI fails to teach or suggest, and fails to anticipate a composition comprising a protein fragment having all of the features recited in amended claim 18. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

#### CONCLUSION

Entry of the above amendments is earnestly solicited. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Please charge the fee of \$156 for the extra independent and dependent claims added herewith to our credit card set forth in the attached Credit Card Payment Form.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any

Docket No. 0591-1010 Appln. No. 10/589,863

additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/H. James Voeller/

H. James Voeller, Reg. No. 48,015 Customer No. 00466 209 Madison Street, Suite 500 Alexandria, VA 22314 Telephone (703) 521-2297 Telefax (703) 685-0573 (703) 979-4709

HJV/lad

# APPENDIX:

The Appendix includes the following item(s):

□ a sequence listing